

IN THE CLAIMS:

1. An implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric release region that controls the release of said therapeutic agent upon administration to a patient, said polymer release region comprising a graft copolymer, which comprises a main chain and a plurality of side chains, wherein one of said main chain and said side chains corresponds to a rubbery phase within said release region at ambient temperatures, and wherein the other of said main chain and said side chains corresponds to a hard phase within said release layer at ambient temperatures.
2. The implantable or insertable medical device of claim 1, wherein said graft copolymer comprises first and second glass transition temperatures, and wherein said first glass transition temperature is below ambient temperature and wherein said second glass transition temperature is above ambient temperature.
3. The implantable or insertable medical device of claim 1, wherein said main chain corresponds to said rubbery phase within said release region and wherein said side chains correspond to said hard phase within said release region.
4. The implantable or insertable medical device of claim 3, wherein said main chain comprises a low  $T_g$  monomer and wherein said side chains comprise a high  $T_g$  monomer.
5. The implantable or insertable medical device of claim 3, wherein said main chain comprises a monomer having a glass transition temperature lower  $0^\circ\text{C}$  when in homopolymer form, and wherein said side chains comprise a monomer having a glass transition temperature higher than  $75^\circ\text{C}$  when in homopolymer form.
6. The implantable or insertable medical device of claim 3, wherein said main chain corresponding to said rubbery phase comprises poly(methyl acrylate), poly(ethyl acrylate) or poly(butyl acrylate) and wherein said side chain corresponding to said hard phase comprises poly(styrene) or poly(methyl methacrylate).

7. The implantable or insertable medical device of claim 1, wherein said main chain corresponds to said hard phase within said release region and wherein said side chains correspond to said rubbery phase within said release region.
8. The implantable or insertable medical device of claim 7, wherein said main chain comprises high  $T_g$  monomer and wherein said side chain comprises a low  $T_g$  monomer.
9. The implantable or insertable medical device of claim 7, wherein said main chain comprises a monomer having a glass transition temperature higher than  $75^{\circ}\text{C}$  when in homopolymer form, and wherein said side chain comprises a monomer having a glass transition temperature lower than  $0^{\circ}\text{C}$  when in homopolymer form.
10. The implantable or insertable medical device of claim 7, wherein said main chain corresponding to said hard phase comprises poly(styrene) or poly(methyl methacrylate) and wherein said side chain corresponding to said rubbery phase comprises poly(methyl acrylate) or poly(butyl acrylate).
11. The implantable or insertable medical device of claim 1, wherein said graft copolymer has an elongation at break of at least 25% at ambient temperature.
12. The implantable or insertable medical device of claim 1, wherein said polymeric release region further comprises a supplementary polymer in addition to said graft copolymer.
13. The implantable or insertable medical device of claim 1, wherein said medical device is sterilized using a quantity of radiation effective to kill pathogens.
14. The implantable or insertable medical device of claim 1, wherein said polymeric release region is a carrier region that comprises said therapeutic agent.

15. The implantable or insertable medical device of claim 1, wherein said polymeric release region is a barrier region disposed over a therapeutic-agent-containing region that comprises said therapeutic agent.
16. The implantable or insertable medical device of claim 1, wherein said polymeric release region is in the form of a coating layer.
17. The implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is selected from a catheter, a guide wire, a balloon, a filter, a stent, a stent graft, a vascular graft, a vascular patch and a shunt.
18. The implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is adapted for implantation or insertion into the coronary vasculature, peripheral vascular system, esophagus, trachea, colon, biliary tract, urinary tract, prostate or brain.
19. The implantable or insertable medical device of claim 1, wherein said therapeutic agent is selected from one or more of the group consisting of an anti-thrombotic agent, an anti-proliferative agent, an anti-inflammatory agent, an anti-migratory agent, an agent affecting extracellular matrix production and organization, an antineoplastic agent, an anti-mitotic agent, an anesthetic agent, an anti-coagulant, a vascular cell growth promoter, a vascular cell growth inhibitor, a cholesterol-lowering agent, a vasodilating agent, and an agent that interferes with endogenous vasoactive mechanisms.